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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,657	12/01/2004	Hajime Yamada	P/2850-101	8759

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
03/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,657	YAMADA ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment and response dated 12-10-09 is acknowledged.

New claims 1-13 are added. Claim 2 has been canceled. Claims 1 and 3-13 are pending.

Response to Amendment

In response to the amendment, the following rejection of record has been withdrawn:

Claims 1, 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0780129 to Yamada et al in view of Griesbach et al (6,875,754), JP 10025240, Schmidt et al (5,578,300), Kludas (5,547,997) and Yvin (5,980,916) as evidenced by EP 0668072 to Kludas.

Yamada et al teach a composition for dermatitis comprising an adrenal cortical steroid, cyclodextrin to solubilize the steroid, and water. The composition comprises 0.025-0.5% adrenal cortical steroid; 0.2-30% cyclodextrin; 0.5-55% of dextran or pullan; and an aqueous solution. The solution may further comprise glucose, mutan, lentinan,

sodium chloride, and potassium chloride, and other polysaccharides. Yamada discloses all of the skin conditions that are claimed in the instant invention (see table 1) and shows that the composition is 90% effective in treating the claimed conditions. Yamada et al do not teach xyloglucan (beta-glucan), trehalose, laminaran (beta-glucan), krestin (beta-glucan), and pectin.

Griesbach et al teach the use of water-soluble beta-glucans as therapeutic agents for skin diseases such as dermatitis, cradle cap, psoriasis, seborrhea sicca, seborrhea oleosa, psoriasis vulgaris, ichtyoses or UV erythemas. See column 3, lines 1-10. The glucans are used in an amount of 0.1-25% and preferably 0.5-15%. See column 3, lines 10-15. Specific glucan include krestin. See table 2. Griesbach teaches away from glucans with 1-6 linkages and thus excludes xyloglucan. The reference also fails to teach laminaran.

Kludas teaches compositions for repair and remodelling of aged and damaged skin, to restore the normal physiological interactions and functioning between various layers of skin (col. 5, L-34-col. 6, L 12). The composition of Kludas comprises pectin, xyloglucan, glucan, cellulose and other plant extracellular matrix components. In particular, Kludas teaches the composition being effective for the treatment of skin and improves luminosity moisturization, satinity and skin elasticity (col. 13, L 9-13), and also states that the above polymers that constitute the carbohydrate polymers of the plant extracellular matrix com (claim 16) repair the damaged dermo-epidermal surface of the skin such that the skin condition is healthy and enhanced because the polymers restore normal physiological function of dermis and epidermis and also improve interaction

between layers of skin. Kludas does not state xyloglucan for treating atopic dermatitis or psoriasis. However, EP 0668072 (also to Kludas), teaches compositions for repair and remodelling of aged and damaged skin, to restore the normal physiological interactions and functioning between various layers of skin (page 3, L 27-37 and page 4, L 23-31). The composition of Kludas comprises pectin, xyloglucan, glucan, cellulose and other plant extracellular matrix components (see page 5, L 41-44 and claim 5). In particular, Kludas teaches the composition being effective for the treatment of conditions such as dermatitis, wound healing, skin damage due to corticosteroids, etc (claim 16). Thus, it is implicit that the composition of Kludas comprising xyloglucan, pectin and other glucans are effective for instant treatment of atopic dermatitis.

Yvin teaches a cosmetic, particularly dermatological, composition comprising effective amounts of laminarin or laminarin-derived oligosaccharides as the active agent for stimulating, regenerating, conditioning and energizing effects on human dermis fibroblasts and human epidermis keratinocytes (abstract, col. 2, L 3-10). Yvin teaches that laminarin can be present in the amounts of 0.00001% to 10% (examples 4-6 and col. 3, L 9-13). While Yvin does not teach laminarin for atopic dermatitis or psoriasis, Yvin teaches that laminarin is capable of stimulating and regenerating dermal fibroblasts and keratinocytes, which is also desired in treating conditions such as atopic dermatitis and psoriasis (see Kludas EP reference which teaches that the ability to repair and remodel dermal and epidermal surfaces leads to visible improvement in the appearance of skin and is beneficial in treating conditions such as dermatitis).

JP '240 while teaching a bath agent teach the use of saccharides such as **glucose,** fructose, sucrose, mannitol, sorbitol, maltitol, xylitol, glucuronic acid, **trehalose**, alginic acid, hyaluronic acid, ribose, arabinose and deoxyribose. Ribose, arabinose and trehalose are preferred used in an amount of 1-100%. JP '240 teaches saccharides have skin moisture retention and are particularly suitable for treatment and prevention of skin diseases including **dermatitis**. See abstract.

Schmidt teaches a method of treating dermatitis using polysaccharides especially pectin in an amount of 0.05-0.5%. See abstract and column 2, lines 50-55. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Yamada et al, Griesbach, JP '240, Kludas, Yvin et al and Schmidt et al and arrive at the instant invention. One would have been motivated to add beta-soluble glucans such as xyloglucan and pectin (Kludas), laminaran (Yvin), and krestin (Griesbach) to Yamada's composition with a reasonable expectation of success since Greisbach teaches beta-glucans treat skin disorders such as dermatitis because Griesbach and Kludas suggest the claimed glucans for skin conditions such as dermatitis and Yvin teaches that laminarin provide regeneration of damaged dermal and epidermal layers of skin. One would have been motivated to also add pectin in the Yamada's composition with a reasonable expectation of success since Schmidt teaches polysaccharides such as pectin treat dermatitis and Yamada suggests the incorporation of polysaccharides in addition to dextran or pullan. Therefore, it is prima facie obvious to further include active compounds that treat dermatitis for an additive effect. Note In re Kerkohoven. "It is prima facie obvious to combine two compositions each of which is

taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Yamada's glucose with the instant trehalose. One would have been motivated to do so with a reasonable expectation of success since Schmidt teach saccharides such as glucose and trehalose treat dermatitis. Therefore, it is prima facie obvious for a skilled artisan to substitute one functional equivalent agent for another since the prior art establishes its functional equivalency.

Response to Arguments

Applicants' arguments dated 12-10-09 have been considered but not found persuasive.

Applicants previous arguments dated 7-6-09 and examiner's response dated 9-11-09 are incorporated by reference. Further, the arguments of 11-4-08 have been addressed by the examiner on 3-3-09 and are incorporated by reference herewith.

It is argued that the treatment of psoriasis vulgaris from the teachings of Yamada is less effective than the results achieved by the instant composition. It was previously argued that more particularly, the cited Yamada et al. reference discloses an effective rate against atopic dermatitis that was only about 95% on average, whereas the rate

obtained with regard to psoriasis vulgaris was only about 90% on average. In the case of the presently claimed composition, however, as taught in the present application effective rates of around 99% were obtained (see, e.g., Table 3 on p. 13).

Applicants' arguments and the unexpected results are not persuasive because firstly, while Yamada teaches 90% efficacy, the efficacy is only limited to the components taught by Yamada, which admittedly lack the components such as trehalose and other glucans of instant claims. If applicants argue that the increase in efficacy to 99% is obtained unexpectedly, it is examiner's position that the effect is not unexpected because the secondary references such as Griesbach, Kludas and JP 240 teach the claimed components for the same purposes i.e., dermatitis and the combination of the teachings of secondary references with that of Yamada would have produced the argued unexpected results because all of the said references teach for the same condition claimed. It is argued that examiner does not appear to give weight to unexpected results because examiner argued that instant claims do not recite percentage of effectiveness. While it is not necessary to recite the effective percentages in the claims, the examiner maintains the position that the results are not unexpected in view of the combination of prior art teachings and also do not show statistical significance. Examiner maintains that the claimed materials are taught by secondary references and that the rejection is over a combination and not on Yamada alone.

It is argued that the various glucans such as krestin of Griesbach are used in comparative examples and showed that oil-in-water skin creams of examples V1 to V7 have lower activity than that the activity of instant composition of example 1. However, it is to be noted that the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Applicants argued that there is no specific disclosure in Griesbach for psoriasis vulgaris, even though the claim 3 of the reference recites psoriasis. It is argued that Griesbach teaches away from glucans with 1-6 linkages and that laminarin and xyloglucan contain 1-6 linkages. Applicants argue that the solutions of include both water soluble beta-(1-3) and beta-(1-6) linkages and that according to Griesbach the components are essential. Applicants' arguments are not persuasive because on one hand applicants argue that the results of Griesbach do not show effectiveness with glucan having 1-6 linkages and on the other hand, it is argued that the results are pertinent to beauty treatment and not treating dermatitis and psoriasis. However, examiner maintains that even with 1-6 linkages, the beta glucans show significant activity (treatment of skin aging tested by Griesbach. If applicants argue that xyloglucan and laminarin according to prior art are not desirable, it is the position of the examiner that applicants only show a collective effect of the glucans in treating atopic dermatitis and psoriasis but not the effect of each of the claimed glucans. Further, applicants argue that the results of Table 2 cannot be extrapolated to atopic

dermatitis. However, Greisbach not only teach beauty treatment but also suggests the role of glucans such as krestin in treating dermatitis and psoriasis (col. 3, L 1-25).

Applicants argue that the new claims exclude oils as they have undesirable effect. In response, except the new claims 10-13, the previously presented claims do not exclude oils and hence the argument is not persuasive. With respect to the new claims, the newly cited prior art shows the undesirable effect of oils.

Applicants argue that only JP 240 teaches treatment for atopic dermatitis and not the other references. Applicants agree that JP 240 teaches treatment of psoriasis. However, it is argued that the reference only teaches as a bath powder, which is unlike an external medicine of the present invention and notes that a bath powder is not an external medicine and not applied directly to the skin, instead dissolved in hot water. It is argued that the amount of trehalose according to JP amounts to 0.00025% and does not teach the instant 0.5 to 55%. Applicants' arguments are not persuasive because if a prima facie case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the prima facie case. See, e.g., In re Dillon, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990). The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Applicants have not provided any evidence to show that bath powders cannot constitute external medicines. With respect to the amounts, JP 240 clearly teaches active agents in the range of 1-100 wt% and applicants have not provided any evidence showing that the claimed amounts are effective whereas outside

the claimed range trehalose is ineffective in treating dermatitis. A skilled artisan would have expected trehalose to treat dermatitis in any amount between 1-100% suggested by JP 240. Thus, it would have been obvious for one skilled in the art to try to optimize the amount of trehalose of JP 240, as a result effective variable, when using in combination with other active agents (Yamada, Griesbach etc.,) because JP teaches any amount between 1-100%.

It is argued that Schmidt teaches allergic contact dermatitis wherein a hydrogen peroxide generating a polymeric material comprising gelatin and pectin is used to induce an oxidative stress and obtain a heat shock response. Schmidt thus utilizes the composition(s) disclosed therein differently than in the case of the presently claimed composition/method. It is argued that Schmidt, thus, does not disclose an external medicine for treating atopic dermatitis and/or psoriasis vulgaris. Applicants' arguments are not persuasive because instant rejection not only cites Schmidt but also cites Kludas EP (evidence) for treating dermatitis with pectin. Thus, pectin while effective to induce an oxidative stress and obtain a heat shock response also is effective for dermatitis treatment as shown by Kludas (EP).

Applicants argue that Kludas (US Patent 554997 and EP 0668072) and Yvin references disclose the use of oils, which according to the instant invention are not preferable. In response, except the new claims 10-13, the previously presented claims do not exclude oils and hence the argument is not persuasive. With respect to the new claims, the newly cited prior art shows the undesirable effect of oils. Applicants argue that the Bar graph (from instant specification) on page 10 of the response compares

closest prior art Yamada. However, the arguments has been addressed in the preceding paragraphs that Yamada is employed by itself in rejecting the claims and instead the claims are rejected over a combination of references, from which the claimed effect would have been expected. Thus, the comparison does not overcome the rejection.

Applicants' arguments regarding the presence of oils in the cited prior art has been addressed and also a new rejection in light of the new claims is as follows

Claim 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0780129 to Yamada et al in view of Griesbach et al (6,875,754), JP 10025240, Schmidt et al (5,578,300), Kludas (5,547,997) and Yvin (5,980,916) as evidenced by EP 0668072 to Kludas, as applied to claims 1 and 3-9 above, in further in view of US 2003/0130248 to Mozzone et al.

The teachings of Yamada, Griesbach, Schmidt, Kludas, Yvin and EP 0668072 to Kludas, discussed above, do not teach oil-free compositions and also fails lacks aqueous solution.

Mozzone et al teaches an aqueous solution which is essentially free of lower alcohol and oil-based components, which contains a water-insoluble anti-inflammatory agent, such as diflorasone diacetate. Mozzone teaches the composition for treating the conditions of scalp, seborrheic dermatitis, pruritis, neurodermatitis (0003). The anti-inflammatory agents include betamethasone (0007).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Yamada et al, Griesbach, JP '240, Kludas, Yvin et al and Schmidt et al and arrive at the instant invention, and further prepare the resulting composition as an oil-free composition and aqueous solution for applying scalp or skin because Mozzone teaches that the composition would not be undesirably grease and sticky to the skin or scalp. A skilled artisan would have expected that the composition of Yamada modified with the teachings of Kludas, Griesbach, JP 240, Yvin and Schmidt would not be greasy and sticky, and yet be able to provide therapeutic effect for treating the same conditions such as those taught by Yamada, Kludas, Griesbach, JP 240, Yvin and Schmidt i.e., dermatitis because Mozzone also teaches the same active agents such as Yamada and for treating the same conditions.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
February 27, 2010